

Message Text

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PAGE 01 STATE 162169
ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-07 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
EA/TIMBS:MEASTON(INFO)

-----047615 262201Z /63

P 262045Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY KUALA LUMPUR PRIORITY

UNCLAS STATE 162169

E.O. 11652:N/A

TAGS: OGEN, ETRD, EIND, TBIO, MY

SUBJECT: FDA ADVISORY - BOND DEFECT IN STERILE DISPOSABLE
SHEATHS (RECALL T-110-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL OF
MEDICAL DEVICE: PRODUCT INVOLVED - MED GENERAL STERILE
DISPOSABLE SHEATH. THE PRODUCT IS USED TO COVER FIBEROPTIC
TUBES (LIGHT PROBES) WHICH ARE USED BY DOCTORS IN HOSPITALS
AND CLINICS IN SITUATIONS WHERE HIGH INTENSITY LIGHT IS
NEEDED, INCLUDING SURGERY. THE PRODUCT IS MANUFACTURED IN
2 FOOT AND 5 FOOT LENGTHS, BUT ONLY THE 5 FOOT LENGTH
SHEATHS ARE BEING RECALLED. THE SHEATHS ARE PACKAGED
INDIVIDUALLY IN PLASTIC PACKAGES WHICH HAVE PAPER
BACKINGS. THEY ARE TERMINALLY STERILIZED.

2. PRODUCT IDENTIFICATION - THE ONLY BRAND NAME UNDER
WHICH THIS PRODUCT IS MANUFACTURED IS, "MED GENERAL, INC.",
7581 METRO PARKWAY, MINNEAPOLIS, MD 55420. THIS IS THE
FIRM'S FORMER ADDRESS. THE FIRM'S CURRENT ADDRESS, MED
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GENERAL INC., 9635 GIRARD AVE. SO., MINNIAPOLIS, MN 55431,
IS PRINTED O' THE CARTONS, EACH CONTAINING 10 SHEATHS.
THREE LOTS ARE BEING RECALLED: 1822, 18,3, 1824. THESE
LOT NUMBERS ARE STAMP:D ON THE INDIVIDUAL PACKAGES.
(MFRD SEPT/DEC, 1977).

3. THE CATALOG NUMBER, 002-1-700, FOR THE SHEATH IS

PRINTED ON THE INDIVIDUAL PACKAGES, CARTONS EACH CONTAINING 10 SHEATHS, AND ON THE CASES EACH CONTAINING 6 CARTONS.

4. MANUFACTURER/RECALLING FIRM: MED GENERAL, INC.,
9635 GIRARD AVE., SO, BLOOMINGTON, MINNEAPOLIS, MN 55431.

THE EXTRUDED TUBING USED IN THE MANUFACTURE OF THE 3 LOTS WAS MANUFACTURED BY TOWER PRODUCTS 1919 SOUTH BUTTERFIELD RD., MINDELEIN, IL 60060.

AFTER THE SHEATHS WERE PACKAGED BY MED GENERAL, INC., THEY WERE SHIPPED TO MICRO-BIOTRIAL COMPANY, 1415 WEST 37TH STREET, CHICAGO, IL 60609 AND TERMINALLY STERILIZED.

MED GENERAL, INC., APPEARS TO BE THE RESPONSIBLE FIRM FOR THE PRODUCT DEFECT.

5. REASON FOR ADVISORY - THE CLOSED OR BONDED END OF THE SHEATH HAS SPLIT APART IN TWO SEPARATE INSTANCES, EXPOSING THE NON-STERILE LIGHT PROBE. ONE OF THESE INSTANCES WAS DURING SURGERY. THERE HAVE BEEN NO INJURIES OR DEATHS ASSOCIATED WITH THIS PRODUCT. THE FIRM LEARNED OF THE PROBLEM THROUGH 2 COMPLAINTS RECEIVED FROM THEIR ACCOUNTS.

6. THE FIRM ADVISED THE FDA OF THE PROBLEM ON 5-10-78, MED GENERAL, INC IS CURRENTLY CONDUCTING TESTS ON THE UNCLASSIFIED

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PRODUCT BUT NO RESULTS ARE AVAILABLE YET.

7. THE RECALL WAS INITIATED ON MAY 12, 1978, BY LETTER TO ALL DIRECT CONSIGNEES. THE FIRM'S RECALL LETTER WITH ATTACHED RESPONSE CARD INSTRUCTS CONSIGNEES TO EXAMINE THEIR STOCK AND CONTACT ALL THEIR ACCOUNTS. CONSIGNEES ARE TO RETURN ALL SHEATHS OF CODES IN QUESTION TO MANUFACTURER. CONTACT AT FIRM IS MR. DEL GARHAM, V.P. OF MANUFACTURER.

8. POST IS REQUESTED TO CONTACT CONSIGNEE TO DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL AND PROCEDURES TO BE FOLLOWED.

9. FOREIGN CONSIGNEE PROVIDED BY FIRM IS: CORONA INTERNATIONAL, CORONA HOUSE, FIRST FLOOR, NO. 125 JALAN SS 15/5A, SUBANY JAZA SELANGOR, MALAYSIA VANCE

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Message Attributes

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Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 26 jun 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE162169
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780265-0432
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780619/aaaaaqlv.tel
Line Count: 110
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Litigation History:
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TAGS: OGEN, ETRD, EIND, TBIO, MY
To: KUALA LUMPUR
Type: TE
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Review Markings:
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